

**AMENDMENTS TO THE DRAWINGS**

**Please replace Figure 1 with the drawing “Replacement Sheet” provided herewith.**

## **REMARKS**

### **Objections to Abstract and Drawings**

The Abstract was objected to because the Examiner stated that it should be in narrative form and consist of 50-150 words. Applicant submits herewith an amended abstract, which is in narrative form and consists of 51 words.

The drawings were objected to for various informalities. Figure 1 had the reference character “2,” which was not mentioned in the specification. Applicant has amended Figure 1 by deleting the reference character “2”. A replacement sheet for Figure 1 is provided herewith. In addition, the Examiner alleged that Claims 27-30 recited various features that were not shown in the Figures. Applicants have canceled Claims 27-30, thereby obviating the objections in relation to these claims.

### **Claim Objections**

Claims 8, 9, 13, 14, 20 and 24 were objected to for various informalities. In particular, recitation of “the inner core” in Claim 8, “the matrix” in Claim 9, “the build up of milk pressures” in Claim 13, “the milk pressure” in Claim 14 and “the body” in Claim 20 lacked antecedent basis. Applicants have canceled Claims 8, 9 and 20. Claim 13 is amended to recite “a build up in milk pressure” and Claim 14 is amended to recite “milk pressure”. Claim 24 was objected to for having a minor grammatical error. Applicants have canceled Claim 24. In view of the claim amendments, the objections are believed to be overcome.

### **Indefiniteness**

Claims 26-31 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant has canceled Claims 26-31, thereby obviating the rejection.

### **Terms**

The Applicant wishes to clarify different terminology used in the present specification and the prior art. In particular, “teat orifice” is the opening at the outside end of the teat. “Teat canal,” “papillary duct” and “streak canal” all refer to the same part of a teat. This is the duct connecting the teat orifice to the teat cistern. The terms “teat cistern” and “teat sinus” are equivalent to each other and describe the reservoir within the teat above the teat canal.

## Anticipation

With respect, the Applicant submits that none of the cited references below anticipate the presently claimed devices and methods. In this regard, the presently disclosed device prevents the development of, or reduces the incidence of infection within the teat. This is achieved by ensuring that the device is configured to be held within the teat streak canal without any protrusions extending beyond the teat orifice's epithelium. The relevance and importance of this feature is that it ensures that the device can not inadvertently act as a bridge to transport bacteria and/or particulate matter into the teat cistern. In contrast, the cited documents all disclose cannulas or teat dilators, which are designed to be inserted into the teat streak canal and have a portion that extends outside of the teat orifice. Such portions outside the teat streak canal can act as a bridge to transport bacteria and/or particulate matter into the teat cistern.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed.Cir. 1986). “[A]nticipation requires that all of the elements and limitations of the claim are found within a single prior art reference.” *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). In view of this requirement, the Applicant comments on the cited references in turn below.

### *Anderson*

Claims 1-6, 9-15, 19, 20 and 31-33 were rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson (U.S. Patent No. 3,938,517). Anderson discloses a teat cautery bullet. The bullet is designed to be inserted into an injured teat of a dairy cow. The cautery bullet of Anderson controls hemorrhaging and prevents the formation of blood clots. The length of the device is between 21 to 23 mm, which is longer than a teat streak canal. This is reinforced by Figure 1, which shows the device's base outside, but adjacent to the teat orifice. The end of the device (Element 22) can clearly be seen within the teat cistern. There is also a clear discussion of the device's base portion (Element 26), which is outside the teat and exposed to air (Column 4, Line 12).

The Applicant has amended the claims to recite that the presently claimed device has no protrusions penetrating outwards beyond an epithelium of the teat orifice. The amended claims reflect that the treatment and control device is configured to be held in position within the teat streak canal such that, once inserted therein, the device has no protrusions penetrating outwards

beyond the epithelium of the teat orifice. These amendments are based on the specification, for example at page 13, line 23 through page 14, line 4, which mentions that the device does not penetrate outwards beyond the external epithelium at the orifice of the teat end. The Applicant notes that Figure 6 of the corresponding PCT Application (PCT/NZ2004/000231) was previously canceled to remove any possible confusion regarding any possible protrusion that penetrates outward beyond an epithelium of a teat orifice.

The teat cautery bullet disclosed by Anderson has a protrusion (i.e., base portion 26) that penetrating outwards beyond an epithelium of a teat orifice. Thus, the limitation that the presently claimed device has no protrusions penetrating outwards beyond an epithelium of the teat orifice is not found within Anderson. As such, the reference does not anticipate the presently claimed device.

#### *Zackheim*

Claims 1-3, 5, 6, 8, 12 and 31 were rejected under 35 U.S.C. § 102(b) as being anticipated by Zackheim (U.S. Patent No. 3,703,898). Zackheim discloses a teat dilator that has a frame formed from elongated, divergent members. The members are configured such that they can be squeezed together to allow insertion of the device into and through the teat canal. The members are resilient such that, once the device has been inserted through the teat canal, they expand to support and separate the teat canal walls. A stop element (20) is used to limit insertion of the dilator into the teat. This prevents the frame extending too far into the cistern which may cause damage to the teat. In addition, the stop element (20) prevents the device passing entirely into the teat canal and its subsequent loss (see column 2, lines 28-33). Zackheim discloses that it is essential that the elongated members forming the frame have a sufficient length that these extend into the cistern (see, column 2 lines 57-65). In addition, shoulders (Element 30) on the elongated members are positioned within the cistern (see column 3 lines 3-5). This is also shown in figures. Moreover, the device disclosed by the Zackheim patent is longer than the teat canal. This is reinforced by Figure 1 showing the stop adjacent to the teat orifice and the frame inside the teat cistern.

Since the dilator of Zackheim has a stop element, such that a grip tab (Element 18) is located outside the teat canal, the reference does not disclose a device as presently claimed, which is held within the teat streak canal and has no protrusion that penetrates outward beyond an epithelium of a teat orifice. Thus, the present claims are not anticipated by Zackheim.

*Sayre*

Claims 1-3, 5, 6, 9-15, 17, 19 and 31 were rejected under 35 U.S.C. § 102(b) as being anticipated by Sayre (U.S. Patent No. 1,957,673). Sayre also discloses a teat dilator. Similar to the devices disclosed in the other references cited, and unlike the presently claimed device, the teat dilator of Sayre has a protrusion that penetrates outwards beyond an epithelium of a teat orifice (i.e., finger piece 4, which limits insertion of the dilator into a teat). Accordingly, Sayre does not anticipate the presently claimed device

*Gordhamer*

Claims 1-3, 5, 6, 8, 12-19, 21-27 and 29-31 were rejected under 35 U.S.C. § 102(b) as being anticipated by Gordhamer (U.S. Patent No. 3,821,956). Gordhamer discloses a bovine teat dilator and medicament dispenser. The dilator has an elongated body having a helical thread extending along its length. A base portion (11) has an annular flange (31), which prevents insertion into the teat canal of the base portion (see, column 3, lines 12-14). Thus, the dilator of Gordhamer has a protrusion that penetrates outwards beyond an epithelium of a teat orifice. As such, the reference does not anticipate the presently claimed device.

Summary

The presently claimed device is intended to sit within the teat canal and act as a barrier to particulate matter and bacteria passing through the teat canal and into the teat cistern. The device is effectively a prophylactic device to prevent the development of infection. In contrast, the citations raised by the examiner are all teat canulas or dilators. They are designed to keep the teat open and remove blockages. The presently claimed device is inserted into a teat during the drying-off period when a cow stops lactating (technically described as involution). It is desirable for the teat to be blocked at this time to prevent infection.

All of the cited documents have base ends or caps. These elements allow the devices to be easily grasped and removed from the teat. The base / cap also ensures that these devices are not fully inserted into the teat canal. As mentioned above, a key inventive aspect of the present invention is that it does not extend beyond the outside orifice of the teat canal once inserted therein. This ensures that there is no protrusion of the device that can act as a bridge or vector for bacteria and particulate matter into the teat cistern. This is in contrast to the cited prior art, which have element that often inadvertently act as conduits for contamination. In addition, the

device acts as a barrier to particulate matter and bacteria passing through the teat canal and into the teat cistern. These two critical differences are reflected in the amended claims and are essential in preventing the development of infection such as mastitis within the teat. The idea of a teat insert that does not extend beyond the teat orifice is not disclosed within any of the prior art cited. In addition, the invention as claimed in amended claim 1 is contrary to the cited documents. This is because all of those documents include a base cap/finger portion that either ensures these are not fully inserted into the teat.

### **Obviousness**

Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sayre (*supra*) in view of Reul et al. (U.S. Patent No. 4,331,651). Claim 28 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Gordhamer (*supra*) in view of Child (U.S. Patent No. 4,385,633).

Without acquiescing and solely to expedite prosecution of the Application, Applicant has canceled Claims 7 and 28. As such, the presently pending claims are not obvious in light of the cited references and the Applicant respectfully requests that the rejections be withdrawn.

### No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

### **CONCLUSION**

In view of Applicants' amendments to the Specification and the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of

the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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